DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0714]

Richard Stowell: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA) is issuing an order under the

Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Richard Stowell for a period of

3 years from importing articles of food or offering such articles for importation into the United

States. FDA bases this order on a finding that Mr. Stowell was convicted, as defined in section

306(1)(1)(B) of the FD&C Act (21 U.S.C. 335a(1)(1)(B)), of three felony counts under Federal

law for conduct relating to the importation into the United States of an article of food. Mr.

Stowell was given notice of the proposed debarment and an opportunity to request a hearing

within the timeframe prescribed by regulation. As of December 14, 2012, Mr. Stowell had not

responded. Mr. Stowell's failure to respond constitutes a waiver of his right to a hearing

concerning this action.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL

REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Kenny Shade,

Office of Regulatory Affairs,

Food and Drug Administration,

12420 Parklawn Dr.,

Rockville, MD 20857,

301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On July 27, 2011, Mr. Stowell was convicted, as defined in section 306(<u>l</u>)(1)(B) of the FD&C Act, when the U.S. District Court for the Southern District of Florida accepted his plea of guilty and entered judgment against him for the following offenses: One count of conspiracy to falsely label and misbrand seafood, in violation of 18 U.S.C. 371; one count of false labeling of seafood under the Lacey Act, in violation of 16 U.S.C. 3372(d)(2) and 3373(d)(3)(A)(ii); and one count of misbranding food, in violation of 21 U.S.C. 331(a), 343(a)(1), and 333(a)(2).

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the importation into the United States of any food. The factual basis for these convictions is as follows: Mr. Stowell was the president and sole shareholder of United Seafood Imports, Inc. (United), a Florida based seafood wholesaler

engaged in various aspects of purchasing, importing, processing, packing, selling, and exporting seafood products, including shrimp.

Beginning in or around January 25, 2007, and continuing through on or about August 7, 2009, Mr. Stowell did knowingly and with the intent to further the object of a conspiracy combine, conspire, confederate, and agree with others to commit an offense against the United States. Specifically, Mr. Stowell's company United purchased approximately one million pounds of shrimp in boxes labeled "Shrimp, Product of Thailand," "Shrimp, Product of Malaysia," and "Shrimp, Product of Indonesia." Mr. Stowell then sent the shrimp to another company, Shifco, and instructed them to repackage and relabel the shrimp as "Shrimp, Product of Panama," "Shrimp, Product of Ecuador," and "Shrimp, Product of Honduras." United, and employees under Mr. Stowell's direction and control, managed and directed the labeling operations of Shifco by providing instructions and other directives to them. Mr. Stowell's company then sold the shrimp that was relabeled to a company who in turn subsequently sold the shrimp to a supermarket chain. This was in violation of 18 U.S.C. 371.

On or about January 26, 2007, Mr. Stowell purchased 180 cases of shrimp valued at approximately \$24,912 and knowingly created and caused to be created individual labels, preprinted bags, and other documents falsely identifying the shrimp as being "Shrimp, Product of Ecuador," when in truth and in fact he knew the shrimp was a product of Malaysia. This was in violation of 16 U.S.C. 3372(d)(2) and 3373(d)(3)(A)(ii).

On or about July 2, 2009, Mr. Stowell knowingly engaged in an offense that involved the introduction and delivery for introduction into interstate commerce of a food that was misbranded, that is, approximately 52 cases of shrimp, with the intent to defraud or mislead, in that Mr. Stowell created and caused to be created individual labels, preprinted bags, and other

documents falsely identifying the shrimp as being a product of Panama when in truth and in fact, he knew the shrimp was a product of Indonesia. This was in violation of 21 U.S.C. 331(a), 333(a)(2), and 343(a)(1).

As a result of his conviction, on September 24, 2012, FDA sent Mr. Stowell a notice by certified mail proposing to debar him for a period of 3 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Stowell was convicted of three felony counts under Federal law for conduct relating to the importation into the United States of an article of food because he: Conspired to falsely label and misbrand seafood, falsely labeled seafood under the Lacey Act, and misbranded food.

The proposal was also based on a determination, after consideration of the factors set forth in section 306(c)(3) of the FD&C Act (21 U.S.C. 335a(c)(3)) that Mr. Stowell should be subject to a 3-year period of debarment. The proposal also offered Mr. Stowell an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Stowell failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, and under authority delegated to the Associate Commissioner (Staff Manual Guide 1410.21), finds that Mr. Richard Stowell has been

convicted of three felony counts under Federal law for conduct relating to the importation of an article of food into the United States and that he is subject to a 3-year period of debarment.

As a result of the foregoing finding, Mr. Stowell is debarred for a period of 3 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Mr. Stowell is a prohibited act.

Any application by Mr. Stowell for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2012-N-0714 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 8, 2013.

Melinda K. Plaisier,

Acting Associate Commissioner for Regulatory Affairs,

Office of Regulatory Affairs.

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